REMARKS

I. Status of the Claims

Claims 11-19 are pending in the application, claims 1-10 having been canceled previously. The claims stand rejected under 35 U.S.C. §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §103

Claims 11-19 stand rejected as obvious over Chouini-Lalanne *et al.* in view of Ajmone-Cat *et al.* Chouini-Lalanne is cited as teaching supercoiled phage DNA, 10 mM NaCl, and one of four different NSAIDs. Ajmone-Cat is cited for teahing the popularity of NSAIDs and that flurbiprofen inhibits PGE_2 production. The examiner argues that it would have been obvious to determine the concentration of chloride ions and the concentration of NSAID in preparing a pharmaceutical. Applicants traverse.

A. Pharmaceutical Formulation

The examiner has indicated that the limitation of pharmaceutical formulation may be properly ignored in interpreting the claims and applying the prior art. Applicants submit that this is not true – limitations must be considered on their merits. Whether a pharmaceutical formulation would be is enough to establish patentability, once considered, is dependent on the facts of a particular case.

In *In re Lerner*, 169 USPQ 51 (CCPA 1971), the court stated that an otherwise unpatenable compound would not be rendered patentable by addition of a carrier or diluent. However, if the use of the carrier would not be obvious, the resulting composition ***could*** be

patentable. *In re Riden et al.*, 138 USPQ 112 (CCPA 1963); *Ex parte Billman*, 71 USPQ 253 (POBA 1946); *Ex parte Erdmann et al.*, 194 USPQ 96 (POBA 1975).

Here, Chouini-Lalanne discloses the use of DNA as a ***target*** for possible phototoxic actions of NSAIDs – an *in vitro* test to ascertain what happens when ***NSAIDs alone*** are administered to a subject. There is no *in vivo* administration of a DNA-NSAID combination discussed or contemplated in this paper. Moreoover, Ajmone-Cat merely discusses NSAIDs, and thus cannot provide any motivation for adding a pharmaceutical carrier to the DNA-NSAID composition of the present invention as that combination of agents is not mentioned, nor would it have any relevance to Ajmone-Cat's teachings.

In short, the pharmaceutical limitation of the present claims must be considered, and when ***properly analyzed under the case law cited above***, it does indeed provide the basis for distinguishing the prior art. This fact alone would establish the patentability of the rejected claims. Reconsideration and withdrawal of the rejection is therefore requested.

B. Motivation to Modify

In addition to the pharmaceutical formulation aspect, claim 1 of the present invention differs from the teachings of Chouini-Lalanne, in at least one respect, by having a pH range of 6.2-7.0, as opposed to 7.4. There is no comparable disclosure of pH ranges in Ajmone-Cat, so the question is one of whether there is sufficient motivation to modify the pH range from 7.4 to at last 7.0. It is well-established that ***some*** motivation must be provided by the examiner - either in the prior art or in the general knowledge in the field. None is present here.

The examiner attempts to skirt this issue by claiming that "optimization" is not patentable. However, applicants submit that even "optimization" requires some motivation – the

case law cited by the examiner does not stand for any proposition that would obviate case law such as *In re Vaeck* which clearly states thiat. Here, looking at Chouini-Lalanne, the reference uses a phosphate buffer to dilute DNA and NSAIDs, and the resulting reaction is performed in a test tube. What motivation is there to drop the pH from the stated 7.4 level to 6.2-7.0? Applicants submit that the answer is ***none***. And because there is no motivation to use a DNA-NSAID composition *in vivo*, the reliance on Ajmone-Cat is of no avail as because it does not discuss using anything but NSAIDs. Thus, the whole discussion of "optimization" is off the point – you can only optimize that for which there is motivation to cause change.

Applicants also point out that this is no mere "tweaking" of the formluation of Chouini-Lalanne. To the contrary, as shown in FIG. 3, by dropping the pH from 7.4 to 7.0, ***an increase in DNA uptake of 50% is observed!*** Surely the examiner will agree that is more than a difference in degree, which even if considered optimization, would not run afoul of the cited cases.

In sum, there is no legal basis to consider the situation presented by the present claims as one of optimization, and even if it were, the facts are such that the claims would still be patentable. Therefore, reconsideration and withdrawal of the rejection is therefore respectfully requested.

III. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should the examiner have any questions regarding the content of this preliminary amendment, a telephone call to the undersigned is invited.

Respectfully submitted,

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Date: January 15, 2008